REMARKS

Claims 1-38 were pending in the present application. Claims 1, 18-23, 29-31, and 35-38 are canceled without prejudice. Applicants reserve the right to prosecute the subject matter of the canceled claims in other applications. Claims 2, 4-7, 10-14, 17, 24, and 26-28 are amended to more particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Claims 2, 4, 5, 7, 10-14, 17, and 26-28 are amended to change their dependency from claim 1 to claim 6, pursuant to the cancellation of claim 1.

Claim 6 has been re-written in independent form, incorporating the limitations of claim 1, now canceled, upon which claim 6 had depended. Accordingly, the scope of claim 6 is unchanged. Claim 6 has also been amended to recite that said "sufficient amount achieves" the physiological response, as suggested by the Examiner with respect to now-canceled claim 1.

Claim 24 is amended to recite poly-β-1→4 N-acetylglucosamine polymers "wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 30 million daltons." Support for this amendment is found in the present specification at page 5, lines 15-18. Claim 24 is also amended to recite that said "sufficient amount achieves" the physiological response rather than said "administering induces" the physiological response, as suggested by the Examiner. Support for this amendment is found in the specification as filed, at page 4, lines 18-24.

Claims 10 and 22 are amended to recite a "poly-β-1→4 N-acetylglucosamine polymer that comprises at least one non-acetylated glucosamine monosaccharide unit, and wherein at least 40% of said glucosamine monosaccharide units are N-acetylated" rather than a "poly-β-1→4 N-acetylglucosamine polymer comprises at least one N-acetylglucosamine monosaccharide that is deacetylated, and wherein at least 40% of said N-acetylglucosamine monosaccharides are acetylated." This amendment is made for clarity and technical accuracy, *i.e.* an N-acetylglucosamine monosaccharide, by definition, is acetylated, and an N-acetylglucosamine monosaccharide that is deacetylated is a glucosamine monosaccharide. Support for these amendments is found at page 24, lines 12-23 of the application as filed. Accordingly, the scope of claims 10 and 22 has not been changed by this amendment.

Therefore all of the amendments are fully supported by the specification as filed and no new matter has been added.

The Rejection under 35 U.S.C. § 112, First Paragraph Should be Withdrawn

Claims 1-5, 11-17, 24-28, 32-34, and 36-38 are rejected under 35 U.S.C. § 112, First Paragraph, as allegedly non-enabled. At page 2 of the Office Action, it is alleged that the specification "does not reasonably provide enablement for a method for achieving at least a transient, localized, modulation of vascular structure and/or function; a method of treating a patient having a vascular disorder; and compositions comprising semi-crystalline poly-β-1→ 4 N-acetylglucosamine polymers of any molecular weight or size."

In reply, Applicants note that independent claim 24, as amended, and claim 6 now re-written in independent form, recite that "the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 30 million daltons." Therefore independent claim 24, as well as claims 25 and 32-34 which depend thereon do not recite methods "comprising semi-crystalline poly-β-1→ 4 N-acetylglucosamine polymers of any molecular weight or size." Similarly, claim 6, which has not been rejected, and claims 2-5, 7, 10-17, and 26-28, which now depend thereon, also do not recite methods "comprising semi-crystalline poly-β-1→ 4 N-acetylglucosamine polymers of any molecular weight or size." Accordingly, claims 2-5, 11-17, 24-28, and 32-34, as amended, are fully enabled, as acknowledged by the Examiner at page 5 of the Office Action. Consequently, Applicants respectfully request that the rejection of claims 2-5, 11-17, 24-28, and 32-34, under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claims 1 and 36-38 are canceled and therefore the rejection of claims 1 and 36-38 under 35 U.S.C. § 112, first paragraph is moot. Accordingly, Applicants respectfully request that the rejection of claims 1 and 36-38 under 35 U.S.C. § 112, first paragraph be withdrawn.

The Rejections Under 35 U.S.C. § 112, Second Paragraph, Should be Withdrawn

Claims 1-38 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. In particular, at page 5 of the Office Action is it alleged that the phrase "sufficient amount," as recited in claims 1 and 24, is unclear.

In reply Applicants note that claim 24 is amended to delete the phrase "administering induces," and to add in its place the phrase "sufficient amount achieves," as suggested by the Examiner. Applicants respectfully submit that claim 24, as amended is not indefinite. Accordingly, Applicants respectfully request that the rejection of claim 24, and therefore claims 25 and 32-34 dependent thereon, as well as non-rejected claim 6 and claims 2-6, 7, 10-17, and 26-28 dependent thereon, under 35 U.S.C. § 112, second paragraph, be withdrawn.

Applicants also note that claim 1 is canceled and therefore the rejection of claim 1 under 35 U.S.C. § 112, second paragraph is moot. Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, second paragraph be withdrawn.

Claims 18-23, 29-31, and 35 are also rejected under 35 U.S.C. § 112, second paragraph, for the reasons provided at page 6 of the Office Action. Although Applicants do not agree with the propriety of this rejection, Applicants note that claims 18-23, 29-31, and 35 are canceled and therefore the rejection of claims 18-23, 29-31, and 35 is moot. Accordingly, Applicants respectfully request that the rejection of claims 18-23, 29-31, and 35 under 35 U.S.C. § 112, second paragraph be withdrawn.

Claims 36-38 are rejected under 35 U.S.C. § 112, second paragraph, for the reasons provided at page 6 of the Office Action. Applicants note that claims 36-38 are canceled and therefore the rejection of claims 36-38 is moot. Accordingly, Applicants respectfully request that the rejection of claims 36-38 under 35 U.S.C. § 112, second paragraph be withdrawn.

The Rejections Under 35 U.S.C. § 103(a) Should be Withdrawn

Claims 1-17, 24-28, and 32-34 are rejected under 35 U.S.C. § 103(a), allegedly as obvious over U.S. Patent No. 5,635,493 to Vournakis *et al.* ("Vournakis"), in view of Barton *et al.* (1999) *Curr. Opin. Nephrol. Hypertens.* 8: 549-556 ("Barton") and Pearson *et al.* (2000) *Lupus* 9: 183-188 ("Pearson"), for the reasons provided below. Applicants respectfully traverse this rejection.

At page 9 of the Office Action the Examiner alleges that

> It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the prior art [Vournakis, Barton, and Pearson] to arrive at the instantly claimed invention. It would have been obvious to one of ordinary skill in the art at the time of the invention that the method described by Vournakis would also induce the release of endothelin-1 and vasoconstriction since Vournakis teaches that the GlcNac materials may be used to promote hemostasis and wound healing, and the prior art [Barton and Pearson] teaches that normal endothelial cell function is critical for all aspects of vascular homeostasis.

At page 10 of the Office Action, the Examiner also contends that

> One would have been motivated to do so [combine the teachings of Vournakis, Barton, and Pearson] in order to treat skin wounds and reduce wrinkles.

The Art Cited in Support of the Rejection Under 35 U.S.C. § 103(a)

Vournakis teaches a method for achieving hemostasis involving administration of a material comprising p-GlcNac which material *inter alia* provides a mechanical matrix that supports and protects clot formation (*see e.g.*, Vournakis, col. 35, lines 38-52). The presently-claimed methods are believed to function, at least in part, independently of the clotting process as stated at page 12, lines 13-16 of the present specification and as demonstrated in the Example provided in Section 17 of the present specification (page 71, line 24 to page 72, line 32).

The Examiner has indicated at page 8 of the Office Action, that *inter alia* Vournakis does not teach compositions causing endothelin-1 release or vasoconstriction. Applicants respectfully submit that, contrary to the Examiner's contention, neither Barton nor Pearson, alone or in combination, overcome the deficiencies of Vournakis.

Pearson provides a summary of the various physiological functions of endothelial cells. In the section beginning with the second column at page 185 and continuing through the second paragraph of the second column at page 186, Pearson describes *inter alia* the control of coagulation and fibrinolysis and the involvement of endothelial cells in those processes. In this section, Pearson describes a number of factors involved in clot formation, clot removal and the regulation thereof, which include: vonWillebrand Factor, P-selectin, prothrombin, thrombin, antithrombin, thrombomodulin, thromboplastin, NO, PGI_2, protein C, tissue plasminogen activator, tissue factor, tissue factor

pathway inhibitor, plasminogen activator inhibitor-1, and coagulation factors Va, VIIIa, and X. However, Pearson does not teach or suggest that induction of endothelin-1 is involved in vasoconstriction or in reduction in blood flow out of a breached vessel. More specifically, Pearson does not teach or suggest, or in fact even mention, any material comprising semi-crystalline pGlcNac, much less the use of such material comprising semi-crystalline pGlcNac for inducing release of endothelin-1, vasoconstriction, or reducing blood flow out of a breached vessel.

Barton describes the role played by endothelin-1 in vasoconstriction and the possible role that increased levels endothelin-1 may play in hypertension and renal disease (*see* the abstract at page 549). However, Barton also does not teach or suggest, or in fact even mention, any material comprising semi-crystalline pGlcNac, much less the use thereof for inducing release of endothelin-1, vasoconstriction, or reducing blood flow out of a breached vessel.

Legal Standards for a Determination of Obviousness Under 35 U.S.C. § 103(a)

In order to support an allegation that an invention is obvious under 35 U.S.C. § 103(a), it must be shown that the "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art."

However, the mere listing of elements or attributes of elements that may be discovered or alleged in the prior art, without more, simply amounts to "hindsight reconstruction ... using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." (*Grain Processing v. American Maize-Products* 5 USPQ2d 1788, 1792 (Fed. Cir. 1992) (citation and internal quotation omitted).

When comparing a claimed invention to the prior art, one must "cast the mind back to the time of the invention," (*In re Dembiczak* 50 USPQ2D 1614, 1617 (Fed. Cir. 1999)) in order to exclude the influence of hindsight on the determination of obviousness. This is particularly important, where, in view of the inventor's disclosure, the invention appears technologically simple. In order to avoid this trap, the Court of Appeals for the Federal Circuit has "made it clear that the best defense against the subtle but powerful

attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine the prior art references." *Id.*

Moreover, the Court of Appeals for the Federal Circuit has also provided that

> Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. (*In re Vaeck* 20 USPQ2d 1438, 1442) (Fed. Cir. 1991) (internal citations omitted)

The Cited Art Does Not Support a Rejection Under 35 U.S.C. § 103(a)

1. There Was No Motivation to Combine the Teaching of Vournakis, Pearson, and Barton

Applicants respectfully submit that there was no motivation to combine the teachings of Vournakis, Pearson, and Barton an attempt to arrive at the presently-claimed invention recited in independent claims 6 and 24.

Vournakis does not teach or suggest the use of materials comprising semi-crystalline p-GlcNac for induction of endothelin-1 production, vasoconstriction, or reduction of blood flow out of a breached blood vessel, in a method that does not depend upon clot formation. Barton and Pearson, even in combination, do not cure this defect since neither reference teaches or suggests (1) that endothelin-1 production and vasoconstriction lead to a reduction of blood flow out of a breached vessel, much less that (2) materials comprising semi-crystalline p-GlcNac could be used for induction of endothelin 1 production, vasoconstriction, and reduction of blood flow out of a breached blood vessel. Therefore, it is clear that Vournakis, Pearson, and Barton do not teach or suggest the methods of claims 6 and 24.

Consequently, Applicants respectfully submit that there is no teaching or even a suggestion in Vournakis, Pearson, and Barton upon which one could base a prediction that topical administration of material comprising semi-crystalline p-GlcNac could induce endothelin 1 production or vasoconstriction, or reduce blood flow out of a breached vessel. Accordingly, Applicants also respectfully submit that there cannot be any motivation to

combine Vournakis, Pearson, and Barton, in an attempt to arrive at the presently-claimed invention since that art, even in combination, does not teach or suggest the presently-claimed methods of claims 6 and 24 for achieving localized, transient, modulation of vascular structure or function or for achieving amelioration of a vascular condition in a patient.

Applicants respectfully submit that, absent the impermissible use of the instant specification as a blueprint, there is no art that teaches or suggests that it would be desirable, or even possible, to combine the teaching of Vournakis, Pearson, and Barton in an attempt to arrive at the presently-claimed methods recited in independent claims 6 and 24.

2. Assuming *Arguendo* That There Was Motivation to Combine the Teaching of Vournakis, Pearson, and Barton, That Combination Would Not Have Provided a Reasonable Expectation of Success to One of Ordinary Skill in the Art

Even, *arguendo*, there were motivation to combine Vournakis with Barton and Pearson, these references do not support the Examiner's inference that it would have been obvious that "the method described by Vournakis would also induce the release of endothelin-1 and vasoconstriction." (Office Action at page 9). As noted above, the cited art, even collectively, does not teach or suggest the methods recited in claims 6 and 24, as amended. Nor is there any teaching or suggestion in the cited art of a correlation between the method of Vournakis involving the use of matrix-forming materials that support clot formation, and the claimed methods reciting endothelin-1 production or vasoconstriction. Consequently, induction of endothelin 1 release, vasoconstriction, and reduction in blood flow out of a breached vessel as a result of topical administration of materials comprising semi-crystalline p-GlcNac, represent completely unexpected results. Therefore, the combined art cited by the Examiner does not teach or suggest all of the elements of the claimed invention. Accordingly, the combination of Vournakis, Pearson, and Barton does not provide one of ordinary skill in the art with a reasonable expectation of achieving the presently-claimed inventions of independent claims 6 and 24 since that collective art does not teach or suggest stimulation of endothelin 1 production, vasoconstriction, and reduction of blood flow out of a breached vessel, by topical administration of semi-crystalline p-GlcNac-containing materials.

Applicants respectfully submit that, for the reasons provided above, one of ordinary skill in the art would not have been motivated to combine the teachings of

Vournakis, Barton, and Pearson, in an attempt to arrive at the presently-claimed invention. Moreover, even assuming *arguendo* that there were any motivation to combine the art cited by the Examiner, one of ordinary skill in the art would not have had a reasonable expectation of success in achieving a transient, localized, modulation of vascular structure and/or function or in ameliorating a vascular disorder in a patient, by topical administration of a material comprising p-GlcNac.

Consequently, Applicants respectfully submit that independent claim 6, and therefore [1] claims 2-5, 7-17, and 26-28 dependent thereon, and independent claim 24, and therefore claims 25 and 32-34 dependent thereon, are not obvious over the combination of Vournakis, Barton, and Pearson. Accordingly, Applicants respectfully request that the rejection of claims 2-17, 24-28, and 32-34 as obvious under 35 U.S.C. § 103(a) over Vournakis, Barton, and Pearson, be withdrawn

Since claim 1 has been canceled, the rejection of claim 1 is moot. Accordingly, Applicants respectfully request that the rejection of claim 1as obvious under 35 U.S.C. § 103(a) over Vournakis, Barton, and Pearson, be withdrawn.

Claims 18-23, 29-31, and 35-38 are rejected under 35 U.S.C. § 103(a), allegedly as obvious over U.S. Patent No. 5,635,493 to Vournakis *et al.* ("Vournakis") for the reasons provided at pages 10-11 of the Office Action.

Although Applicants do not agree that this rejection is proper, Applicants note that claims 18-23, 29-31, and 35-38 have been canceled, and therefore, the rejection of 18-23, 29-31, and 35-38 under 35 U.S.C. § 103(a) over Vournakis is moot. Accordingly, Applicants respectfully request that the rejection of claims 18-23, 29-31, and 35-38 as obvious under 35 U.S.C. § 103(a) over Vournakis, be withdrawn.

CONCLUSION

Applicants believe that no fee is due for this submission other than the fee for an extension of time. However, should the Commissioner determine that a fee is due, please charge the required amount to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Applicants believe that each ground for rejection of the pending claims has been successfully overcome, obviated, or rendered moot. Accordingly, Applicants

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[1] "Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious." *In re Fine* 5 USPQ2d 1596, 1600 (Fed. Cir. 1988)

respectfully request that the rejection of claims 1-5, 11-17, 24-28, 32-34, and 36-38 under 35 U.S.C. § 112, first paragraph, the rejection of claims 1-38 under 35 U.S.C. § 112, second paragraph, and the rejection of claims 1-38 under 35 U.S.C. § 103, be withdrawn. Applicants submit that the entire application in now in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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Date: February 10, 2003

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Enclosure

Application of: Vournakis *et al.*

Serial No.: 09/781,182 Group Art Unit: 1614

Filed: February 12, 2001 Examiner: P. T. Lewis, Ph.D.

For: COMPOSITIONS AND METHODS FOR MODULATION OF VASCULAR STRUCTURE AND/OR FUNCTION Attorney Docket No.: 7867-022-999

Confirmation No.: 2779

Appendix A: Marked-up Version of the Claims Amended Herein

Matter that has been deleted is enclosed in brackets, and matter that has been added is underlined.

1. (Canceled)

2. (Amended) The method of claim [1] 6, wherein the physiological response comprises stimulation of endothelin-1 release.

4. (Amended) The method of claim [1] 6, wherein the physiological response comprises vasoconstriction.

5. (Amended) The method of claim [1] 6, wherein the physiological response comprises reduction in blood flow out of a breached vessel.

6. (Amended) [The method of claim 1] A method for achieving at least a transient, localized, modulation of vascular structure and/or function, comprising:

topically administering to a patient in need of said modulation, a sufficient amount of material comprising semi-crystalline poly-β-1→4 N-acetylglucosamine polymers, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 30 million daltons, and wherein said sufficient amount achieves at least a transient, localized physiological response selected from the group consisting of stimulation of endothelin-1 release, vasoconstriction, and reduction in blood flow out of a breached vessel,

whereby the patient experiences at least a transient, localized modulation of vascular structure and/or function.

7. (Amended) The method of claim [6] 1, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 50,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 10 million daltons.

10. (Amended) The method of claim [6] 1, wherein the semi-crystalline poly-β-1→4 N-acetylglucosamine polymer comprises at least one [N-acetylglucosamine monosaccharide that is deacetylated] non-acetylated glucosamine monosaccharide unit, and wherein at least 40% of said [N-acetylglucosamine monosaccharides are acetylated] glucosamine monosaccharide units are N-acetylated.

11. (Amended) The method of claim [1] 6, wherein the patient is a human.

12. (Amended) The method of claim [1] 6, wherein the material is in the form of a gel, sponge, film, membrane, foam, spray, emulsion, suspension, or solution.

13. (Amended) The method of claim [1] 6, wherein the material is applied directly to a blood vessel.

14. (Amended) The method of claim [1] 6, wherein the vascular structure is a blood vessel selected from the group consisting of capillary, vein, and artery.

17. (Amended) The method of claim [1] 6, wherein the extent of the transient, localized modulation of vascular structure and/or function is substantially proportional to the amount of semi-crystalline poly-β-1→4 N-acetylglucosamine administered.

18. - 23. (Canceled).

24. (Amended) A method for treating a patient having a vascular disorder, comprising:

topically administering to a patient in need of such treatment, a sufficient amount of material comprising semi-crystalline poly-β-1→4 N-acetylglucosamine polymers, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 30 million daltons, and wherein said [administering induces] sufficient amount achieves at least a transient, localized physiological response selected from the group consisting of stimulation of endothelin-1 release, vasoconstriction, and reduction in blood flow out of a breached vessel, whereby the patient experiences at least a transient, localized modulation of vascular structure and/or function,

whereby said administering ameliorates said vascular condition.

26. (Amended) The method of claim [1] 6, wherein said polymers are substantially free of protein.

27. (Amended) The method of claim [1] 6, wherein said polymers are substantially free of organic contaminants.

28. (Amended) The method of claim [1] 6, wherein said polymers are substantially free of inorganic contaminants.

29. - 31. (Canceled).

35. - 38. (Canceled).

Appendix B: The Claims as They Will be Pending
Upon Entry of the Present Amendment Dated February 10, 2003

2. (Amended) The method of claim 6, wherein the physiological response comprises stimulation of endothelin-1 release.

3. The method of claim 2, wherein the endothelin-1 is released from vascular endothelial cells.

4. (Amended) The method of claim 6, wherein the physiological response comprises vasoconstriction.

5. (Amended) The method of claim 6, wherein the physiological response comprises reduction in blood flow out of a breached vessel.

6. (Amended) A method for achieving at least a transient, localized, modulation of vascular structure and/or function, comprising:

topically administering to a patient in need of said modulation, a sufficient amount of material comprising semi-crystalline poly-β-1→4 N-acetylglucosamine polymers, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 30 million daltons, and wherein said sufficient amount achieves at least a transient, localized physiological response selected from the group consisting of stimulation of endothelin-1 release, vasoconstriction, and reduction in blood flow out of a breached vessel,

whereby the patient experiences at least a transient, localized modulation of vascular structure and/or function.

7. (Amended) The method of claim 6, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 50,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 10 million daltons.

8. The method of claim 7, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 10,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 2 million daltons.

9. The method of claim 8, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 4,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 800,000 daltons.

10. (Amended) The method of claim 6, wherein the semi-crystalline poly-β-1→4 N-acetylglucosamine polymer comprises at least one non-acetylated glucosamine monosaccharide unit, and wherein at least 40% of the glucosamine monosaccharide units are N-acetylated.

11. (Amended) The method of claim 6, wherein the patient is a human.

12. (Amended) The method of claim 6, wherein the material is in the form of a gel, sponge, film, membrane, foam, spray, emulsion, suspension, or solution.

13. (Amended) The method of claim 6, wherein the material is applied directly to a blood vessel.

14. (Amended) The method of claim 6, wherein the vascular structure is a blood vessel selected from the group consisting of capillary, vein, and artery.

15. The method of claim 14, wherein the blood vessel is a breached blood vessel.

16. The method of claim 15, whereby the patient experiences cessation of bleeding.

17. (Amended) The method of claim 6, wherein the extent of the transient, localized modulation of vascular structure and/or function is substantially proportional to the amount of semi-crystalline poly-β-1→4 N-acetylglucosamine administered.

24. (Amended) A method for treating a patient having a vascular disorder, comprising:

topically administering to a patient in need of such treatment, a sufficient amount of material comprising semi-crystalline poly-β-1→4 N-acetylglucosamine polymers, wherein the poly-β-1→4 N-acetylglucosamine polymer comprises about 50 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β-1→4 conformation, and said polymer has a molecular weight of about 10,000 daltons to about 30 million daltons, and wherein said sufficient amount achieves at least a transient, localized physiological response selected from the group consisting of stimulation of endothelin-1 release, vasoconstriction, and reduction in blood flow out of a breached vessel, whereby the patient experiences at least a transient, localized modulation of vascular structure and/or function,

whereby said administering ameliorates said vascular condition.

25. The method of claim 24, wherein the vascular disorder is selected from the group consisting of menorrhagia, cerebral aneurysm, abdominal aneurysm, uterine fibroid lesion, and blood vessel puncture.

26. (Amended) The method of claim 6, wherein said polymers are substantially free of protein.

27. (Amended) The method of claim 6, wherein said polymers are substantially free of organic contaminants.

28. (Amended) The method of claim 6, wherein said polymers are substantially free of inorganic contaminants.

32. The method of claim 24, wherein said polymers are substantially free of protein.

33. The method of claim 24, wherein said polymers are substantially free of organic contaminants.

34. The method of claim 24, wherein said polymers are substantially free of inorganic contaminants.